IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD., Plaintiff, v. SAREPTA THERAPEUTICS, INC., Defendant.	C.A. No. 21-1015 (JLH) [redacted] REDACTED - PUBLIC VERSION
SAREPTA THERAPEUTICS, INC. and THE UNIVERSITY OF WESTERN AUSTRALIA, Defendant/Counter-Plaintiffs, v. NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC. Plaintiff/Counter-Defendants.	

SAREPTA THERAPEUTICS, INC. AND THE UNIVERSITY OF WESTERN AUSTRALIA'S REPLY BRIEF IN SUPPORT OF THEIR MOTIONS TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF PLAINTIFF/COUNTER-DEFENDANTS' EXPERTS

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TABLE OF CONTENTS

[redacted]

TABLE OF AUTHORITIES

Page(s)

CASES

[redacted]

TABLE OF ABBREVIATIONS

Abbreviation	Description
'851 Patent	U.S. Patent No. 9,994,851
Sarepta	Defendant/Counter-Plaintiff Sarepta Therapeutics, Inc.
UWA	Counter-Plaintiff The University of Western Australia
NS	Plaintiff/Counter-Defendants Nippon Shinyaku Co., Ltd. and NS Pharma, Inc.
Patent Office	United States Patent and Trademark Office
ASO	Antisense Oligonucleotide
POSA	Person of Ordinary Skill in the Art
Asserted Claim	Claim 1 of U.S. Patent No. 9,994,851
Ex. ___	Exhibit ___
Br.	D.I. 611 (Sarepta's Opening *Daubert* Brief)
Opp.	D.I. 623 (NS's Opposition to Sarepta's *Daubert* Brief)
Bold and Italic	Emphasis added unless indicated otherwise

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NS's Opposition confirms that Sarepta's *Daubert* motions should be granted. NS admits its experts are now employing a new claim construction for "morpholino ASO" that diverges from their prior sworn opinions. NS's experts were right the first time: morpholinos are PMOs, as both the intrinsic and extrinsic evidence show. Similarly, NS flip-flops on the nature of Dr. Wood's opinions and testimony. NS now claims they "center on interpreting the '851 patent from the perspective of a POSA—a topic that is directly relevant to NS's lack of written description arguments." Opp. 9. But NS previously represented that "Dr. Wood is ***not*** opining on the invalidity of the Sarepta/UWA Asserted Patents under the written description requirement." D.I. 387 at 2 (emphasis in original). And Dr. Wood applies an ***inventorship*** standard, which has no relevance to this case. NS's attempts to defend Dr. Hastings's enablement and written description opinions fare no better, for the reasons below. All these opinions—desperate attempts to create new invalidity positions after NS's primary argument was gutted by the Court—should be excluded.

I. *MOTION #1*: EXCLUSION OF NS'S EXPERT OPINIONS AND TESTIMONY APPLYING A NEW AND IMPROPER CONSTRUCTION OF "MORPHOLINO"

NS admits that its experts applied a new construction of "morpholino." *See* Opp. 1-3. And NS likewise concedes that at least some of their opinions and testimony are "directly based on a broader interpretation of 'morpholino.'" Opp. 8. Because NS's new construction is incorrect, Drs. Hastings and Wood's opinions and testimony concerning it should be excluded under Rule 702.

A. The Plain and Ordinary Meaning of "Morpholino ASO" Is a PMO

NS contends that "morpholino" is a generic term that encompasses "multiple types of intersubunit linkages and is not limited to PMOs." Opp. 6. But the intrinsic and extrinsic records show the opposite. Years before this case, the applicants defined the term for the Patent Office, stating "the term 'morpholino antisense oligonucleotide' refers to the chemical structure of the oligonucleotide backbone in which six-membered morpholine rings replace ribose ***and***

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nucleotides are joined by phosphorodiamidate linkages." D.I. 612-1, Ex. 10 ('007 File History) at SRPT-VYDS-0247403; *see also* D.I. 612-1, Ex. 15 ('851 File History) at SRPT-VYDS-0003101 (similar). NS ***ignores*** the applicants' definition, which alone is fatal to its position.

Nor does NS meaningfully dispute that the file histories include citations to prior art confirming that "morpholino ASO" refers to PMOs. D.I. 611 at 6-8; Opp. 4-5. While NS spends pages on figures that Dr. Hastings ignored during claim construction, it admits that Summerton 1997 "focus[ed] on the phosphorodiamidate [linkages] shown in Figure 2 as our ***principle*** [sic] ***linkage type***."[1] *See* Opp. 4; D.I. 612-1, Ex. 2 (Summerton 1997) at SRPT-VYDS-0229439. And NS does not rebut that Heasman 2002 and Gebski 2003, both submitted to the Patent Office to support the definition of "morpholino antisense oligonucleotide," equate "morpholino ASO" with "PMO." Opp. 5. Nor does NS dispute that Aarstma-Rus uses "morpholino" and "[m]orpholino-phosphorodiamidate" interchangeably. Opp. 6. All of these references decisively confirm that the plain and ordinary meaning of "morpholino ASO" in June 2005 was PMO.

Even more, NS concedes (as it must) that its experts "elect[ed] to use the terms morpholino and PMO[] interchangeably" in their prior sworn opinions. Opp. 5. That is the point. Presented with (and in some instances citing) the same intrinsic and extrinsic evidence that is before the Court now, Drs. Hastings and Wood used the plain and ordinary meaning of "morpholino ASO" in 2005, which meant PMOs specifically. D.I. 171, Ex. 43 ¶ 110; D.I. 612-1, Ex. 1 ¶ 55. Only after the Court revised its claim construction did NS's experts change their tune.

Essentially ignoring this mountain of evidence, NS myopically focuses on Hudziak (U.S. Pat. No. 6,784,291), asserting that it supports a broad reading of "morpholino." Opp. 5.

[1] NS's experts concede that Summerton 1997 focuses on PMOs. D.I. 171, Ex. 43 ¶ 111; D.I. 612-1, Ex. 5 (Wood Supp. Tr.) at 117:2-119:6.

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Unlike Heasman 2002 and Gebski 2003, Hudziak was not submitted to the Patent Office to support the definition of morpholino ASO. In any event, it does not support NS's belated construction. Hudziak repeatedly confirms "morpholino" preferentially refers to ASOs with phosphorodiamidate linkages. D.I. 612-1, Ex. 8 at Abstract ("The antisense compound is RNase-inactive, and is preferably a ***phosphorodiamidate-linked*** morpholino oligonucleotide."); *see also id.* at 2:20-26, 4:8-15, 6:48-55, 17:6-13, 21:32-41. That unrelated inventors in an unrelated patent application proffered their own definition for use in their patent does not change the term's plain and ordinary meaning. The statements and cited art in the prosecution history confirm that the inventors used the plain meaning for "morpholino ASO," namely PMOs. *See* D.I. 612-1, Exs. 10, 15; *see also* Opp. 3.

B. Drs. Hastings and Wood's Opinions and Testimony Broadly Incorporate Their New Understanding of "Morpholino"

NS contends that the correct "morpholino" definition "would only affect a small subset" of Drs. Hastings and Wood's opinions. Their reports say otherwise. NS concedes that many report paragraphs directly fall within the scope of Sarepta's motion.[2] Opp. 8. Each remaining challenged paragraph also implicates NS's new "morpholino" construction expressly or by reference:

- Opinions that expressly implicate possible intersubunit variations or that Drs. Hastings and Wood may use to reference such variations in connection with claim scope. *E.g.*, D.I. 612-1, Ex. 4 (Hastings Supp. Op. Rep.) ¶ 80 (intersubunit linkages "***further increases the number of possible 'morpholino backbones'*** that an ASO could have, while still falling within the scope of the claims."); *id*. at ¶ 188 ('851 Patent claims "***encompass[] more than just PMO***."); *id.* at ¶¶ 81, 83, 123-24, 184, 194-95, 203, 206-07, 214-16; D.I. 612-1, Ex. 17 (Hastings Supp. Reply Rep.) ¶¶ 49, 91; D.I. 612-1, Ex. 7 (Wood Supp. Op. Rep.) ¶¶ 27, 28, 77; D.I. 612-1, Ex. 6 (Wood Supp. Reply Rep.) ¶¶ 14, 65, 82.

[2] NS asserts that its experts do not rely on their new understanding of "morpholino" in multiple paragraphs. Opp. 6-8. If the Court accepts NS's assertion, it should preclude Drs. Hastings and Wood from offering any contrary opinion or testimony at trial (e.g., referring to genus scope, written description, or enablement with reference to their expansive "morpholino" construction).

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- Descriptions of arguments to the PTO cited for the purpose of artificially inflating the size of the claimed genus via intersubunit linkages. D.I. 612-1 (Hastings Supp. Op. Rep.) ¶ 104 (unpredictability "caused by variations in at least . . . internucleotide linkages.")
- Opinions that initially "exclude" intersubunit linkage variations but clarify in subsequent statements that such calculations are "conservatively low." *E.g.,* Ex. 612-1, Ex. 17 (Hastings Supp. Reply Rep.) at ¶ 13 ("these estimates are conservatively low, as they . . . do not account for variations in inter-subunit linkages."); 14-16, 111; *see also* D.I. 623 at 6 (referencing similar paragraphs from Hastings Supp. Op. Rep.).
- Descriptions of intersubunit linkages as potential chemical modifications to ASOs. *E.g.,* Ex. 612-1, Ex. 17 (Hastings Supp. Reply Rep.) ¶¶ 93, 117.
- Ultimate opinions that may implicate testimony on intersubunit variations. *E.g.,* D.I. 612-1, Ex. 4 (Hastings Supp. Op. Rep.) ¶ 126 ("in my opinion, the specification fails to disclose a common structural feature of the ***claimed morpholino antisense oligonucleotides***"); *id.* at ¶ 217; D.I. 612-1, Ex. 17 (Hastings Supp. Reply Rep.) ¶¶ 79, 85, 119.

The Court should exclude NS and its experts from relying on their improper definition of "morpholino ASO" for any and all purposes.

II. ***MOTION #2*: EXCLUSION OF DR. WOOD'S IRRELEVANT AND UNHELPFUL OPINIONS AND TESTIMONY**

Despite bearing the burden, NS fails to establish that Dr. Wood's analysis—which applies an irrelevant legal standard—meets the "fit" requirement of Rule 702 or that any conceivable probative value outweighs the danger of confusing the issues, misleading the jury, or needlessly presenting cumulative evidence as required by Rules 403 and 702.

"An expert's opinion that crucially depends on an incorrect legal theory is not likely to be relevant to the Court's fact-finding. Consequently, courts routinely preclude those portions of an expert's report that are premised on a misunderstanding of the law." *Exela Pharma Sci., LLC v. Eton Pharms., Inc.*, C.A. No. 20-365-MN, 2022 WL 806524, at *3 (D. Del. Feb. 8, 2022) (collecting cases). That is the case here. While NS argues that Dr. Wood's opinions "center on interpreting the '851 patent from the perspective of a POSA—a topic that is directly relevant to NS's lack of written description arguments" and cites various cases on written description (Opp. 9), that is not the legal standard Dr. Wood applied, as can be seen in a simple comparison:

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Dr. Wood's legal standard (D.I. 612-1, Ex. 16 (Wood Op. Rep.) ¶ 16)	***Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc)**
B. <u>Inventorship</u> 16. I am informed that ***inventorship occurs when an inventor forms in his mind a definite and permanent idea*** of the complete and operative invention, as it is hereafter to be applied in practice. An idea is definite and permanent when the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue. I am informed that in an unpredictable field like antisense oligonucleotides for exon skipping, ***the inventor must contemporaneously recognize and appreciate the invention,*** and the invention must have known utility for there to be invention.	"In other words, the test for sufficiency is ***whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date***. [citation omitted] The term 'possession,' however, has never been very enlightening. It implies that as long as one can produce records documenting a written description of a claimed invention, one can show possession. ***But the hallmark of written description is disclosure. Thus, 'possession as shown in the disclosure' is a more complete formulation***. Yet whatever the specific articulation, the test requires ***an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art***. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed."

Whether an inventor had a "definite and permanent" idea of the invention or "contemporaneously recognize[d] and appreciate[d] the invention"—Dr. Wood's legal standard—is not an analysis of "possession as shown in the disclosure" using an "objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art," which is the written description standard. That Dr. Wood ultimately used buzzwords from the written description standard (like "possession") does not change that he used the wrong legal analysis to arrive at those opinions. *See* D.I. 612-1, Ex. 6 (Wood Supp. Reply Rep.) ¶ 82. Dr. Wood admitted he is not opining on written description, enablement, or validity. D.I. 612-1, Ex. 5 (Wood Supp. Tr.) at 31:14-16 ("Q. You're not offering any opinions on the written description requirement, correct? A. That's correct."); *id.* at 31:17-19 (no opinions on enablement); *id.* at 31:10-13 (no opinions concerning validity). Yet, NS now claims Dr. Wood's opinions on what "the inventors and POSAs would 'recognize and appreciate' … is exactly what is required under the written description standard." Opp. 11. In other words, NS intends to introduce Dr. Wood's opinions and

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testimony as evidence of an analysis[3] Dr. Wood did not perform. NS's explanation of Dr. Wood's testimony and how it allegedly fits in would confuse ***anybody***—certainly including the jury.

Sarepta did not "concede" that Dr. Wood's opinions and testimony were "pertinent to evaluating written description." Opp. 1. NS previously asserted "[n]owhere in any report does Dr. Wood opine on the invalidity of the Sarepta Asserted Patents," and "it should be clear from the reports themselves that Dr. Wood is ***not*** opining on the invalidity of the Sarepta/UWA Asserted Patents under the written description requirement." D.I. 387 at 2 (emphasis original). In response, Sarepta noted that, "[a]lthough the word 'invalid' does not appear in Dr. Wood's reports, his opinions employ the language used in cases holding claims invalid under § 112." D.I. 389 at 1-2. It is NS—not Sarepta—that has done an about-face on the nature of Dr. Wood's testimony.[4]

NS's brief also confirms that it will not suffer prejudice if Dr. Wood's opinions and testimony are excluded. NS does not even assert that it will be prejudiced. At most, NS complains that it "should not be prevented from trying its case in the manner of its choosing" (Opp. 12), including presenting testimony from both Dr. Hastings (who purports to apply written description and enablement standards in her analysis) and Dr. Wood (who "offers his own methodology and independent analysis"), Opp. 11-12. But NS's desire to try its case as it chooses does not absolve

[3] NS is incorrect that written description assesses what "the inventors and POSAs would 'recognize and appreciate.'" The correct standard assesses a skilled artisan's analysis of the specification.

[4] NS incorrectly asserts Sarepta "acquiesced to Dr. Wood testifying about the '851 patent." Opp. 8. Sarepta did no such thing. The portion of the transcript NS cites was lifted from a discussion on whether Dr. Wood should be permitted to opine on ***other patents***, not at issue in this case and it supports Sarepta's position that Dr. Wood's interference declaration should be excluded: Dr. Wood's declaration "in the interference proceeding that w[as] made in support of the invalidity of [an] unrelated patent application from a different entity that's not party to this suit and that had a different priority date from the" asserted patents should be excluded due to their potential for confusion. D.I. 570 at 38:13-39:12. To be clear, Dr. Wood should not be permitted to testify, but if he is, his testimony must be limited to the patents-in-suit and, by his own sworn testimony, cannot extend to issues of written description, enablement or validity; this begs the question of how his testimony would be helpful to the trier of fact.

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it from complying with Rules 702 and 403, or from its burden to prove that Dr. Wood's opinions and testimony meet the standards for admissibility. Considering the significant risk of confusing or misleading the jury, the absence of any probative value of Dr. Wood's opinions applying an irrelevant inventorship standard, and the lack of prejudice to NS because it can still put on its invalidity case, the Court should exclude Dr. Wood's opinions and testimony.

III. *MOTION #3*: EXCLUSION OF DR. HASTINGS'S OPINIONS AND TESTIMONY CONCERNING ENABLEMENT OF 5'- AND 3'-END MODIFICATIONS

NS stretches the enablement requirement well beyond the boundaries of the law. NS argues that the '851 Patent must enable 5'- and 3'-end modifications, despite the undisputed fact that such modifications are not recited in the claims. As explained in Sarepta's brief and below, NS's view of the law is erroneous and would lead to an untenable outcome: any claim that includes the term "comprising" would be susceptible to an enablement challenge based on overbreadth.

NS's reliance on the (non-binding) holding of *Baxalta* is misguided. Opp. 13. That case did not address unrecited elements—let alone hold they must be enabled. NS argues that the Court considered enablement of "'humanized and chimeric antibodies,' 'bispecific antibodies,' as well as antibodies of various isotypes—none of which were specified by the claim language." *Id*. That is wrong. Claims 3 and 4 ***expressly recited*** those antibodies (and others). *Baxalta Inc. v. Genentech, Inc.*, 579 F. Supp. 3d 595, 601, 609, 622 (D. Del. 2022). Moreover, those antibodies were part of the "antibody or antibody fragment" element recited in every claim. *Id*. Here, the claims recite an "antisense oligonucleotide," with no mention of end modifications. Such modifications are not recited in the claims, nor are they required; they are distinct chemical groups that could optionally conjugate to the ASO. D.I. 612-1, Ex. 4 (Hastings Supp. Op. Rep.) ¶ 55. As explained in Sarepta's brief, courts have consistently held that a patent need not enable unrecited elements. Otherwise essentially all "comprising" claims would be in jeopardy.

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NS fails to distinguish the controlling precedent. NS argues that *W.L. Gore* is "so old as to predate modern enablement law." Opp. 14. But NS does not identify any "modern" decision that overrules *W.L. Gore* and the Supreme Court relied on much older cases in the recent *Amgen Inc. v. Sanofi* decision. 598 U.S. 594, 605 (2023) ("While the technologies [in cases from 1846-1928] may seem a world away . . . the decisions are no less instructive for it."). In fact, the Federal Circuit reached the same conclusion as recently as 2023. *United Therapeutics Corp. v. Liquidia Techs., Inc.*, 74 F.4th 1360, 1370-71 (Fed. Cir. 2023), *cert. denied*, 144 S. Ct. 873 (2024).

NS also resorts to trivial factual distinctions to argue that the controlling law is "not on point." Opp. 14. NS argues that those cases did not involve genus claims. *Id*. That is a red herring. The question here is not whether species within a genus must be enabled; it is whether distinct unrecited elements must be enabled. The caselaw makes clear that the answer is no. The Court should exclude Dr. Hastings's opinions and testimony that apply the wrong legal standard.[5]

IV. ***MOTION #4*: EXCLUSION OF DR. HASTINGS'S OPINIONS AND TESTIMONY APPLYING INCORRECT WRITTEN DESCRIPTION LAW**

A. Dr. Hastings's Opinions and Testimony Are Not an Objective Inquiry into the Four Corners of the Specification and Should Be Excluded

NS fails to justify Dr. Hastings's subjective opinions and their disconnect from the four corners of the patent. First, as NS admits,[6] the analysis of written description may not be "untethered to the inventors' own description of the invention." *Allergan USA, Inc. v. MSN Lab'ys*

[5] NS argues in passing that any "exclusion would have to be narrow because Dr. Hastings's end cap modifications analysis is also relevant to her written description opinion." Opp. 14-15. Not so. The same rationale applies for written description. Dr. Hastings admits the '851 Patent literally describes 5'- and 3'-end modifications. D.I. 612-1, Ex. 4 (Hastings Supp. Op. Rep.) ¶¶ 55-58. Her written description opinion is based on another flawed premise—that the patent does not include examples with such modifications (*see id*. at ¶ 106)—which is addressed *infra* in Motion #4.

[6] Critically, NS's positions here are ***fatal*** to its own *Daubert* motion against Dr. Dowdy (D.I. 613), for NS now ***admits*** extrinsic evidence may be considered in the written description context, if tethered to the specification (Opp. 15). This renders NS's *Daubert* motion dead on arrival.

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Priv. Ltd., 111 F.4th 1358, 1376 (Fed. Cir. 2024); Opp. 15. Dr. Hastings read the inventor's own description of the invention in the specification (that there was exon 53 skipping), then went hunting outside the specification to try to find something she could use to contradict the inventor's description. *See* Br. 16-17. Such speculative hunting is not "tethered to the specification." If it were, ***anything*** could be "tethered to the specification" because ***anything*** could be used to try to contradict the specification. Dr. Hastings did not need to apply her own subjective analysis of [redacted] to "shed light on the interpretation or significance of the data in the UWA Patents" (Opp. 15), because the Wilton inventors said the claimed ASO sequences caused exon 53 skipping in the specification (*see* Br. 16-17, 19). Second, [redacted] prophetic examples are sufficient to meet the written description requirement. *Ariad Pharms.*, 598 F.3d at 1352; *Alcon Rsch. Ltd. v. Barr Lab'ys, Inc.*, 745 F.3d 1180, 1191 (Fed. Cir. 2014); *see infra* Section IV.B. Dr. Hastings may not simply reject what the patent literally says.

NS's cases are inapt. In *Immunex,* the Federal Circuit rejected Sandoz's claim that an analysis relied on outside information, stating "[i]t is well-established that a patent specification need not re-describe known prior art concepts." 964 F.3d 1049, 1064 (Fed. Cir. 2020). It also rejected Sandoz's argument that later amendments showed there was no actual possession at the time of invention, stating "the district court correctly noted that actual reduction to practice is not required to show possession." *Id.* In *Biogen*, the court agreed that the specification did not literally show possession where Biogen had "selectively pluck[ed] specific words from the specification that correspond to each element of the claimed invention." No. 1:17CV116, 2020 WL 3317105, at *13 (N.D.W. Va. June 18, 2020). Only ***after*** finding no description in the specification did the court look to extrinsic evidence to "illuminate[] the absence of critical description." *Id.* Here,

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Dr. Hastings used her subjective interpretation of extrinsic data to try to undermine the actual patent disclosure that there was exon 53 skipping. This is contrary to law and should be excluded.

B. Dr. Hastings's Opinions and Testimony Requiring Proof of Therapeutic Efficacy and Evidence of Exon Skipping Should Be Excluded

NS ignores Federal Circuit precedent, quoted in Sarepta's brief, that "written description is about whether the skilled reader of the patent disclosure can recognize that what was claimed corresponds to what was described; it is not about whether the patentee has proven . . . that the invention works." *Alcon Rsch.*, 745 F.3d at 1191; *Allergan*, 111 F.4th at 1376; Br. 18-19; Opp. 17 n.2 (claiming "the only case Sarepta cites [is] *In re Brana*"). As explained in Sarepta's brief, the Asserted Claim does not require that ASOs induce therapeutic levels of exon skipping. Br. 19. As the Federal Circuit recently recognized, "because safety and efficacy are not recited in the claims, we need not deal with" arguments that written description is lacking where the specification does not describe treating patients. *United Therapeutics*, 74 F. 4th at 1371. Because clinical data is not needed to show that what was claimed corresponds to what was described, Dr. Hastings misapplies written description law and her opinions and testimony should be excluded.

NS's cited cases (*LizardTech*, *Juno*, *AbbVie*, *University of Rochester,* and *UroPep*, Opp. 17-18) are inapt. None relate to whether a claim to a drug compound that ***does not recite*** a therapeutic efficacy requirement is nevertheless insufficiently described if the specification ***does not include*** a disclosure of therapeutic efficacy. In contrast, *Alcon* and *United Therapeutics* are on point and control. Dr. Hastings's opinions are thus contrary to law and should be excluded.

V. CONCLUSION

Sarepta and UWA respectfully request that the Court exclude the opinions and testimony of the NS experts as described above and in their opening brief and accompanying motions.

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October 23, 2024

CERTIFICATE OF SERVICE

I hereby certify that on October 23, 2024, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

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